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DR. WILLIAM ATKINSON:

The majority of the influenza vaccine available in the U.S. is inactivated subunit vaccine. The three types of subunit vaccine available contain either split virus, or purified hemagglutinin. A live attenuated influenza vaccine administered by nasal spray is also available again this year. We will discuss this vaccine in more detail in a few minutes.

Both types of influenza vaccine - inactivated and live attenuated vaccine- contain the same 3 influenza viruses, two type A viruses and one type B. The viruses in both types of influenza vaccine are grown in embryonated hens eggs, and both vaccines contain residual egg protein.

The inactivated influenza vaccination schedule is relatively simple- one INTRAMUSCULAR dose per year. But the dose is not the same for all age groups, and some recipients need 2 doses. Here is the routine schedule for inactivated influenza vaccine, which we will abbreviate TIV. The minimum age is 6 months. No influenza vaccine is approved for children younger than 6 months. Children 6 months through 35 months of age receive a dose of zero point 25 milliliter- half the dose of an older child and adult. Recipients 3 years of age and older should receive a one-half milliliter dose. Children 6 months through 8 years of age receiving influenza vaccine for the first time should receive 2 doses, separated by one month. The first dose is an immunologic primer. Two doses are not necessary for persons 9 years or older, because by this age our immune systems have been primed by infection with wild type influenza virus. What if a child is receiving influenza vaccine for the first time, and does not return for the second dose a month later. Does the child need one or two doses the following year? Fortunately, you can count last year's dose as the primer dose. The child needs only one dose this year, and in subsequent years.

Thimerosal, a mercury containing compound used as a preservative in some vaccines, continues to draw public attention. Although there is no evidence that thimerosal in vaccines leads to serious adverse events in recipients, manufacturers have removed it from most vaccines. Thimerosal free influenza vaccine will be available for the 2006-2007 season. Sanofi Pasteur produces Fluzone. Fluzone is available in three presentations - a multidose vial that contains thimerosal as a preservative and may be administered to anyone 6 months of age or older. Fluzone

is also available in two thimerosal-free formulations - a single dose syringe with a 0.25 milliliter pediatric dose of vaccine for children 6 through 35 months of age, and a single dose syringe and vial with a 0.5 milliliter dose for persons 36 months and older. Fluvirin is produced by Novartis, formerly the Chiron Corporation. Fluvirin is available in 2 formulations. The Fluvirin multidose vial contains thimerosal, and a single dose syringe that contains only a trace of thimerosal, which does not function as a preservative. Both Fluvirin formulations are approved for persons 4 years and older. Fluarix is produced by GlaxoSmithKline and is available only in a single dose syringe. Fluarix is approved for persons 18 years and older. Fluarix contains a trace of thimerosal. You should be careful to administer these vaccines only to persons in the age group for which they are approved. If you intend to vaccinate children younger than 4 years of age you MUST use Fluzone. Neither Fluvirin nor Fluarix is approved for children this age, and ACIP does NOT recommend use of these vaccines outside their approved age ranges. ACIP believes that because of the known risks for severe illness from influenza infection, the benefit of influenza vaccine with reduced OR STANDARD thimerosal content outweighs the theoretical risk, if any, from thimerosal.

Andrew?

ANDREW KROGER:

In June 2003, the Food and Drug Administration approved this country's first live attenuated influenza vaccine, which we will refer to as LAIV. The vaccine is produced by MedImmune and marketed as FluMist.

ACIP encourages the use of LAIV in eligible persons, including healthcare personnel, to help increase the amount of inactivated influenza vaccine available for high risk groups. We hope that more of you will be using LAIV - or receiving it - this year. So we want to review the characteristics and recommendations for the use of this product. LAIV is trivalent, and contains the same virus strains included in inactivated influenza vaccine. It does not contain thimerosal or gelatin but does contain egg protein. LAIV has been demonstrated to reduce culture confirmed influenza, febrile otitis media, and antibiotic use in children. It also reduces febrile upper respiratory tract episodes, lost work days, and antibiotic use among adult recipients. However, there is no evidence at this time that LAIV reduces febrile illness or culture confirmed influenza more effectively than inactivated influenza vaccine.

This table shows the vaccination schedule for LAIV based on age

and prior influenza vaccination history. A dose of LAIV is 0.5 milliliter, regardless of age, divided equally between nostrils. Children 5 through 8 years of age who have received NO previous influenza vaccine- either LAIV or inactivated influenza vaccine- should receive two doses of LAIV separated by 6 to 10 weeks. Note that this is longer than the 4 weeks recommended between the first two doses of inactivated influenza vaccine. ACIP recommends that children 5 through 8 years of age previously vaccinated at any time with either LAIV or inactivated influenza vaccine receive one dose of LAIV. They do not require a second dose. This is different than the manufacturer's labeling, which recommends that children who have not previously received LAIV should receive two doses, regardless of whether they may have previously received inactivated influenza vaccine. Persons 9 through 49 years of age should receive one dose of LAIV. LAIV is currently approved for use ONLY for healthy persons 5 years through 49 years of age who are not pregnant. This group includes healthcare personnel and other persons in close contact with high-risk groups, such as household contacts. The vaccine is also an option for persons who want to reduce their risk of influenza. These persons now have the option of choosing either TIV or LAIV. LAIV should NOT be administered to children younger than 5 years, or adults 50 years of age and older. It also should not be used in anyone with an underlying medical condition that increases the person's risk of complications of influenza. TIV should be used for these groups. LAIV contains egg protein so should not be administered to a person with anaphylactic egg allergy.

Because LAIV contains live attenuated influenza viruses there have been concerns about transmission of live attenuated influenza vaccine viruses to close contacts, particularly in a healthcare setting. These concerns have been unfounded. CDC has received no reports of transmission of vaccine viruses, in any setting. As a result ACIP recommends that eligible healthcare personnel and others with close contact with high-risk persons, including immunosuppressed persons, consider receiving LAIV. There is one exception to this. Inactivated influenza vaccine is preferred ONLY for close contacts of SEVERELY immunosuppressed persons who require care in a protective environment. Practically, this means that healthcare personnel and others who have contact with hematopoietic stem cell transplant patients while in isolation should not receive LAIV. This preference is because of the theoretical risk that a live attenuated vaccine virus could be transmitted to the severely immunosuppressed individual and cause disease. Persons who receive LAIV, including healthcare personnel, should refrain from contact with

severely immunosuppressed persons for 7 days after vaccination. This precaution is to avoid exposing the immunosuppressed person to the vaccine virus. We have heard about several instances of LAIV recipients being banned from entering hospitals. This is not necessary. ACIP recommends that persons who receive LAIV need NOT be excluded from visitation of patients who are not severely immunosuppressed or have other medical conditions. LAIV can be administered simultaneously with any other live or inactivated vaccine. LAIV may be administered to persons with minor acute illnesses, such as mild upper respiratory tract infection with or without fever. However, if nasal congestion is present which might impede delivery of the vaccine to the nasopharyngeal mucosa, deferral of administration should be considered until the condition improves. Bill?

ATKINSON:

The vaccine viruses in LAIV are extremely fragile, so storage and handling of this vaccine is critical. The viruses in LAIV have no tolerance for heat. LAIV must be stored at 5 degrees Fahrenheit, which is minus 15 degrees Celsius, or colder at all times. The vaccine may be stored in a frost-free freezer. The special manufacturer-supplied freezer box is no longer required for storage in a frost free freezer. You should keep the vaccine frozen until immediately before it is used, at which time you will thaw it in your hand. Do not roll the sprayer between your hands because you can dislodge the plunger or dose divider clip. LAIV may also be thawed in a refrigerator. LAIV can be stored at refrigerator temperature - which is 35 to 46 degrees Fahrenheit or 2 to 8 degrees Celsius for up to 60 hours prior to use. Thawed vaccine cannot be refrozen. Any LAIV that is kept at refrigerator temperature more than 60 hours must be discarded. Because LAIV is administered intranasally using a sprayer device, low level contamination of the environment with vaccine virus is probably unavoidable. This has caused concern about unintentional exposure to persons administering the vaccine. The risk of acquiring vaccine virus from the environment is not known but is likely to be limited. ACIP recommends that severely immunosuppressed persons should not administer LAIV. Practically, that means that if a person is immunocompetent enough to go to work, he or she is immunocompetent enough to administer LAIV.

Other persons at increased risk of complications of influenza may administer LAIV, including pregnant women, persons with asthma, and persons 50 years of age and older. Gloves and masks are not required. We do not have time during this program to discuss antiviral drugs for the prevention or treatment of influenza virus infection. However, one issue you should be

aware of is increasing resistance to 2 antiviral drugs. The CDC influenza laboratory has detected high levels of resistance to amantadine and rimantadine among influenza A viruses. Amantadine is marketed with the brand name Symmetrel, and rimantadine with the brand name Flumadine. This discovery necessitates a change in recommendations for the use of these drugs. CDC now recommends that neither amantadine nor rimantadine be used for the treatment or chemoprophylaxis of influenza A infections in the United States during the 2006- 2007 influenza season. During this period, oseltamivir, brand name Tamiflu, or zanamivir, brand name Relenza, should be prescribed if an antiviral drug is indicated for the treatment or chemoprophylaxis of influenza. More information on this issue is available in the 2006 influenza ACIP statement.

It is not possible to predict the severity of the influenza season in any given year. But we can be certain that there will be outbreaks this winter. We are hopeful that there will be plenty of influenza vaccine this year, and that we will be ready for the virus when it arrives.

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